

another survey of the provider's or supplier's compliance with specified Medicare conditions or requirements before taking the enforcement actions provided for at § 488.24.

(3) If CMS determines that a provider or supplier is not in compliance with applicable Medicare conditions or requirements, the provider or supplier may be subject to termination of the provider or supplier agreement under § 489.53 of this chapter or of the supplier agreement in accordance with the applicable supplier conditions and any other applicable intermediate sanctions and remedies.

(d) *Re-instating deemed status.* An accredited provider or supplier will be deemed to meet the applicable Medicare conditions or requirements in accordance with this section if all of the following requirements are met:

(1) It withdraws any prior refusal to authorize its accrediting organization to release a copy of the provider's or supplier's current accreditation survey.

(2) It withdraws any prior refusal to allow a validation survey, if applicable.

(3) CMS finds that the provider or supplier meets all applicable Medicare CoP, CfC, conditions of certification, or requirements.

(e) *Impact of adverse actions.* The existence of any performance review, comparability review, deemed status review, probationary period, or any other action by CMS, does not affect or limit conducting any validation survey.

[80 FR 29839, May 22, 2015]

§ 488.10 State survey agency review: Statutory provisions.

(a) Section 1864(a) of the Act requires the Secretary to enter into an agreement with any State that is able and willing to do so, under which appropriate State or local survey agencies will determine whether:

(1) Providers or prospective providers meet the Medicare conditions of participation or requirements (for SNFs and NFs);

(2) Suppliers meet the conditions for coverage; and

(3) Rural health clinics meet the conditions of certification.

(b) Section 1865(a) of the Act provides that if an institution is accredited by a

national accrediting organization recognized by the Secretary, it may be deemed to have met the applicable conditions or requirements.

(c) Section 1864(c) of the Act authorizes the Secretary to enter into agreements with state survey agencies for the purpose of conducting validation surveys in institutions accredited by an accreditation program recognized by the Secretary.

(d) Section 1865(c) provides that an accredited institution that is found after a validation survey to have significant deficiencies related to health and safety of patients will no longer meet the applicable conditions or requirements.

[53 FR 22859, June 17, 1988, as amended at 56 FR 48879, Sept. 26, 1991; 58 FR 61842, Nov. 23, 1993; 62 FR 46037, Aug. 29, 1997; 80 FR 29839, May 22, 2015]

§ 488.11 State survey agency functions.

State and local agencies that have agreements under section 1864(a) of the Act perform the following functions:

(a) Survey and make recommendations regarding the issues listed in § 488.10.

(b) Conduct validation surveys of deemed status providers and suppliers as provided in § 488.9.

(c) Perform other surveys and carry out other appropriate activities and certify their findings to CMS.

(d) Make recommendations regarding the effective dates of provider agreements and supplier approvals in accordance with § 489.13 of this chapter.

[62 FR 43936, Aug. 18, 1997, as amended at 80 FR 29839, May 22, 2015]

§ 488.12 Effect of survey agency certification.

Certifications by the State survey agency represent recommendations to CMS.

(a) On the basis of these recommendations, CMS will determine whether:

(1) A provider or supplier is eligible to participate in or be covered under the Medicare program; or

(2) A provider or supplier accredited under a CMS-approved accreditation program remains deemed to meet the Medicare conditions or requirements, or will be placed under the jurisdiction

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of the SA and subject to further enforcement actions in accordance with the provisions at § 488.9.

(b) Notice of CMS's determination will be sent to the provider or supplier.

[53 FR 22859, June 17, 1988, as amended at 80 FR 29839, May 22, 2015]

§ 488.13 Loss of accreditation.

If an accrediting organization notifies CMS that it is terminating a provider or supplier due to non-compliance with its CMS-approved accreditation requirements, the SA will conduct a full review in a timely manner.

[80 FR 29839, May 22, 2015]

§ 488.14 Effect of QIO review.

When a QIO is conducting review activities under section 1154 of the Act and part 466 of this chapter, its activities are in lieu of the utilization review and evaluation activities required of health care institutions under sections 1861(e)(6), and 1861(k) of the Act.

[59 FR 56237, Nov. 10, 1994]

§ 488.18 Documentation of findings.

(a) The findings of the State agency with respect to each of the conditions of participation, requirements (for SNFs and NFs), or conditions for coverage must be adequately documented. When the State agency certifies to the Secretary that a provider or supplier is not in compliance with the conditions or requirements (for SNFs and NFs), and therefore not eligible to participate in the program, such documentation includes, in addition to the description of the specific deficiencies which resulted in the agency's recommendation, any provider or supplier response.

(b) If a provider or supplier is certified by the State agency as in compliance with the conditions or participation requirements (for SNFs and NFs) or as meeting the requirements for special certification (see § 488.54), with deficiencies not adversely affecting the health and safety of patients, the following information will be incorporated into the finding:

(1) A statement of the deficiencies that were found.

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(2) A description of further action that is required to remove the deficiencies.

(3) A time-phased plan of correction developed by the provider and supplier and concurred with by the State agency.

(4) A scheduled time for a resurvey of the institution or agency to be conducted by the State agency within 90 days following the completion of the survey.

(c) If, on the basis of the State certification, the Secretary determines that the provider or supplier is eligible to participate, the information described in paragraph (b) of this section will be incorporated into a notice of eligibility to the provider or supplier.

(d) If the State agency receives information to the effect that a hospital or a critical access hospital (as defined in section 1861(mm)(1) of the Act) has violated § 489.24 of this chapter, the State agency is to report the information to CMS promptly.

[39 FR 2251, Jan. 17, 1974. Redesignated at 39 FR 11419, Mar. 28, 1974, and further redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 53 FR 23100, June 17, 1988; 59 FR 32120, June 22, 1994; 59 FR 56237, Nov. 10, 1994; 62 FR 46037, Aug. 29, 1997]

EFFECTIVE DATE NOTE: At 59 FR 32120, June 22, 1994, in § 488.18, paragraph (d) was added. The amendment contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 488.20 Periodic review of compliance and approval.

(a) Determinations by CMS to the effect that a provider or supplier is in compliance with the conditions of participation, or requirements (for SNFs and NFs), or the conditions for coverage are made as often as CMS deems necessary and may be more or less than a 12-month period, except for SNFs, NFs and HHAs. (See § 488.308 for special rules for SNFs and NFs.)

(b) The responsibilities of State survey agencies in the review and certification of compliance are as follows:

(1) Resurvey providers or suppliers as frequently as necessary to ascertain compliance and confirm the correction of deficiencies;